

EXHIBIT 2

1 in order to calculate this 2,060 percent increased risk?

2 **A.** So what I think I hear you saying is that if you knew from
3 a study or if you knew and you read that the risk was
4 1 percent, what would you need to do to figure out how big that
5 increase was?

6 And, yes, you would have to know that. And then you would
7 have to do the math to figure it out, which is, in some ways,
8 simply arithmetic, but it's not something that I think most --
9 most physicians would walk around knowing what the background
10 premise of spina bifida is. So as a epidemiologist, we knew
11 that. We looked it up in our studies and we calculated it, but
12 I think it would be a pretty rare physician who would be able
13 to take the 1 percent and say, Ah, that's a 20-fold increase.
14 I think, you know, one in a million, but not very many.

15 **Q.** So the -- and the 20.6, that's the same as the 2,060
16 percent increase, right?

17 **A.** Yes.

18 **Q.** And as an epidemiologist and a physician, is that an
19 important number that you think for physicians that they should
20 know?

21 **A.** Yes.

22 **Q.** Okay. Do you know of any other cause of spina bifida,
23 known cause, other than valproic acid?

24 **A.** Yes.

25 **Q.** What is that?

1 MR. WILLIAMS: Thank you.

2 Q. (BY MR. WILLIAMS:) Dr. Oakley, remember earlier, I didn't
3 have this book -- about 10,000 drugs in there?

4 A. Yes, sir.

5 Q. You are familiar with this as a physician, et cetera?

6 A. Yes, sir.

7 Q. Of those 10,000 drugs, the top -- in the top three would
8 you put valproic acid?

9 A. As far as causing birth defects, yes.

10 Q. I want to -- I asked you earlier -- we were talking about
11 folic acid, and I guess I forgot to ask you the ultimate -- the
12 real question. I don't know if we ever explained to the jury
13 what your role was in getting folic acid into the food supply.
14 What role did you actually play?

15 A. Well, I was head of the birth defects group at CDC. I had
16 this lovely group of men and women that worked for me that were
17 just tremendous. And we knew from the moment we had that
18 telephone call that we needed to get folic acid into flour, so
19 we went to work to figure out how to do that. And that meant
20 basically getting to know the people in the nutrition side of
21 the FDA and their regulatory process. And it took us a while,
22 and we needed the March of Dimes to finally help get us past
23 the political barriers that were at the FDA, but, in fact, we
24 kept bringing the information and kept plugging away and kept
25 doing whatever needed to be done to get this job done.

1 **A.** We did. We said we would set up a registry if we could do
2 that, and we, I think, included in one of our articles our
3 telephone number.

4 **Q.** And did it fail?

5 **A.** It did.

6 **Q.** And why?

7 **A.** Well, because I think we didn't put enough money into it,
8 for one reason, and enough attention to it. And the volunteers
9 didn't ring our telephone and say I've got someone you ought to
10 put in your registry.

11 **Q.** And did -- was there a request made by the FDA to Abbott to
12 put the phone number --

13 **MR. BALL:** Excuse me, your Honor. This calls for
14 hearsay, FDA to Abbott.

15 **MR. WILLIAMS:** Well, let me get to the document.

16 **THE COURT:** Okay. Well, it's overruled at this time.
17 I don't even know -- he hasn't finished the question.

18 **MR. WILLIAMS:** Yes.

19 **Q. (BY MR. WILLIAMS:)** Was there a request to Abbott to put in
20 their documents their label and their letters to the doctors
21 the phone number for your registry so that you could help
22 recruit?

23 **A.** I think I've seen a piece of paper with that on it, but I
24 don't remember it right this minute.

25 **Q.** Okay. Let me refresh your memory. Let me get that.

1 MR. BALL: I'll just renew the hearsay objection.

2 THE COURT: Your objection is noted.

3 **Q. (BY MR. WILLIAMS:)** Exhibit 104, which is a TRIP report
4 produced by Abbott to us in this case, sir. Let me show you.
5 1982. The subject is Depakene teratogenicity, Depakene spina
6 bifida, same as -- Depakene, same as Depakote contains valproic
7 acid, right?

8 **A.** Yes. I'm sorry. I was seeing Dr. Frances Kelsey's name
9 there.

10 **Q.** And this was 1982?

11 **A.** Yes.

12 **Q.** And this was a TRIP report, people attended from the FDA?

13 **A.** Yes.

14 **Q.** I don't know if you were in this or not.

15 **A.** I was not in it, no.

16 **Q.** And Abbott had people attending, right?

17 **A.** That's what it says, yep.

18 **Q.** And it goes back, shows the background about their first
19 knowledge about Dr. Robert, correct?

20 **A.** Yes.

21 **Q.** And I'd like to go to this paragraph: Of interest to the
22 FDA, is the registry initiated by the CDC? That was you,
23 right?

24 **A.** Yes.

25 **Q.** And: The FDA suggested that we incorporate the phone

1 number for this registry in our letter. This was an Abbott
2 document, right?

3 A. Yes.

4 Q. Did they ever put the phone number for your registry in
5 their letter to doctors?

6 A. Not that I'm aware of.

7 Q. Do you know why they would refuse back in 1982 to assist
8 you in starting a registry?

9 A. Say that again, please.

10 Q. Do you know why, back in 1982, they would refuse to assist
11 you in starting a registry?

12 A. I don't know why.

13 Q. Before -- could a registry have been started to follow up
14 on birth defects as far back as 1982?

15 A. Yes.

16 Q. If one -- the sooner one starts a registry -- a collection
17 of data, does it make sense to you the sooner one will
18 receive -- get information?

19 A. It seems like common sense to me.

20 Q. And over the years, has it turned out that -- are there
21 more birth defects associated with valproic acid than just
22 spina bifida?

23 A. Yes.

24 Q. So in 1982, spina bifida was confirmed as a birth defect
25 resulting from valproic acid, I think you've testified, right?

1 think as a result of those contacts, Abbott traveled
2 Dr. McMahon to Atlanta to meet with me and to discuss those
3 data. And those were my sort of direct contacts with that
4 group of people.

5 Q. And there in the fall of 1982, when Abbott was -- became
6 aware of this data, they engaged consultants from Harvard and
7 Yale, right?

8 A. They did.

9 Q. And the consultants from Harvard and Yale said -- they
10 raised some questions about whether Dr. Robert's information
11 was scientifically reliable, right?

12 A. Well, as I recall the conversation with Dr. McMahon, he
13 came to view our data and as I ended up -- or Roberts' data --
14 I said that these data look very strong to me. I can't make
15 this go away. And he agreed with that at that time.

16 Q. Okay. And so at that point in time, after consulting with
17 you and communicating with you, and communicating with the
18 folks from Harvard and Yale, these experts from Harvard and
19 Yale. Abbott had two choices. The studies that were being
20 proposed by the people at Harvard and Yale would take several
21 years to implement, wouldn't they?

22 A. They would take a while, yes.

23 Q. And they could wait -- Abbott could wait for those studies,
24 or they could put information about this new risk into the
25 label, true?

1 **A.** That's true.

2 **Q.** And they elected to, within a matter of a few months, put
3 this new significant risk into the label, true?

4 **A.** They did.

5 **Q.** And also sent it in this Dear Doctor letter, as
6 Mr. Williams calls it, that he showed you, right?

7 **A.** Yes.

8 **Q.** And in that letter was a specific risk of spina bifida,
9 right?

10 **A.** That is correct.

11 **Q.** And that was a risk that was calculated by you all at the
12 CDC.

13 **A.** That's correct.

14 **Q.** In 1982?

15 **A.** That is correct.

16 **Q.** Now, our case here involved -- and that was 1.2 percent,
17 right?

18 **A.** Yes. It got changed to 1 to 2 someplace along the way.

19 **Q.** Right. At some point not too long after that, it got
20 refined to kind of a 1 to 2 range.

21 **A.** Yes.

22 **Q.** And that risk of 1 to 2 percent is old and accurate, isn't
23 it, sir?

24 **A.** It is old and it's pretty good, yes.

25 **Q.** Yeah. And, in fact, that is --

1 2,060 percent, true?

2 A. That is correct.

3 Q. Okay. The only person that you are familiar with that has
4 referred to it as 2,060 percent is Mr. Williams; is that right?

5 A. Well, percents are used in other things, but it certainly
6 was a way that -- it is saying the same thing.

7 Q. But the way you deal with it, in your professional
8 capacity, would not be 2,060 percent?

9 A. I would usually say 20-fold, yeah.

10 Q. So what you need to do in order to determine what the odds
11 ratio is, is you need the background rate, right?

12 A. Yep.

13 Q. And you need the incident rate, right?

14 A. Yep.

15 Q. So if we know that the incident rate is -- for something,
16 for example, is 1 to 2 percent, and we know the background rate
17 is .1 to .2 percent, then the odds ratio is 10 to 20 times,
18 right?

19 A. Under those assumptions.

20 Q. Right. So if you were told there's an incident rate of 1
21 to 2 percent and there's a background rate of .1 to .2, you
22 would be able to determine fairly easily that the odds ratio is
23 10 to 20 times, right?

24 A. Say that again, please.

25 Q. If you were told these numbers -- 1 to 2 percent, .1 to